EXHIBIT 3

510(k) Premarket Notification

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Device Classification Name	system, test, blood glucose, over the counter[22]
510(k) Number	K181131
Device Name	Accu-Chek Guide Me Blood Glucose Monitoring System
Applicant	Roche Diabetes Care 9115 Hague Road Indianapolis, IN 46250
Applicant Contact	Ginger Emrich
Correspondent	Roche Diabetes Care 9115 Hague Road Indianapolis, IN 46250
Correspondent Contact	Ginger Emrich
Regulation Number	862.1345[23]
Classification Product Code	NBW[24]
Date Received	04/30/2018
Decision Date	12/13/2018
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	Clinical Chemistry
510k Review Panel	Clinical Chemistry
Summary	Summary[25]
FDA Review	Decision Summary[26]
Type	Special
Reviewed by Third Party	No
Combination Product	No

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Page Last Updated: 05/06/2024

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U.S. Food and Drug Administration
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Silver Spring, MD 20993
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